No. 10-972

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE WEBLOG *PATENT DOCS* AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

I. The Federal Circuit's Rigid *Per Se* Rule Precludes the Courts and the Patent Office from Considering the Particular Facts and Circumstances of Each Case When Determining Whether Obviousness-Type Double Patenting Exists 3

II. The Federal Circuit Decision Has Eviscerated the Obviousness-Type Double Patenting Doctrine by Collapsing It into Obviousness under 35 U.S.C. § 103 8

III. The Federal Circuit Has Misapplied the Law by Transforming A Composition Claim into Method Claims for All Uses Disclosed in the Specification 10

IV. The Decision below Creates A Bright-Line Rule That Undermines Public Policy Underlying the Patent System and Curtails Innovation 13

CONCLUSION 16

TABLE OF AUTHORITIES

Page(s)

CASES

Ansonia Brass & Copper Co. v. Elec. Supply Co.,
144 U.S. 11 (1892) 14

Beckman Instruments, Inc. v. LKB Produkter AB,
892 F.2d 1547 (Fed. Cir. 1989) 6

In re Basell Poliolefine Italia S.P.A.,
547 F.3d 1371 (Fed. Cir. 2008) 14

Bilski v. Kappos,
130 S.Ct. 3218 (2010) 7

Catalina Marketing International, Inc. v. Cool Savings.com, Inc.,
289 F.3d 801 (Fed. Cir. 2002) 14

eBay Inc. v. MercExchange, L.L.C.,
547 U.S. 388 (2006) 7

General Foods Corp. v. Studiengesellschaft Kohle GmbH,
972 F.2d 1272 (Fed. Cir. 1992) 6, 9

Geo M. Martin Co. v. Alliance Machine Systems, Intern. LLC,
618 F.3d 1294 (Fed. Cir. 2010) 6

Graham v. John Deere Co.,
383 U.S. 1 (1966) 9

In re Kaplan,
789 F.2d 1574 (Fed. Cir. 1986) 3, 4, 7, 9

Knoll Pharm. Co. v. Teva Pharms. USA, Inc.,
367 F.3d 1381 (Fed. Cir. 2004) 15

KSR Int'l Co. v. Teleflex Inc.,
550 U.S. 398 (2007) 7

In re Kumar,
418 F.3d 1361 (Fed. Cir. 2005) 6

McCarty v. Lehigh Val. R. Co.,
160 U.S. 110 (1895) 11

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) 7

Motion Picture Patents Co. v. Universal Film Mfg. Co.,
243 U.S. 502 (1917) 13

Motorola, Inc. v. Interdigital Tech. Corp.,
121 F.3d 1461 (Fed. Cir. 1997) 6

Pfaff v. Wells Electronics, Inc.,
525 U.S. 55 (1998) 13

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) 10

Rockwell Intern. Corp. v. U.S.,
147 F.3d 1358 (Fed. Cir. 1998) 6

Quanta Computer, Inc. v. LG Electronics, Inc.,
553 U.S. 617 (2008) 13

SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.,
242 F.3d 1337 (Fed. Cir. 2001) 10

Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.,
611 F.3d 1381 (Fed. Cir. 2010) .....*passim*

Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.,
625 F.3d 719 (Fed. Cir. 2010) 5

Winans v. Denmead,
56 U.S. 330 (1853) 11, 12

STATUTES

35 U.S.C. § 101 .....7, 13

35 U.S.C. § 102(a) 8

35 U.S.C. § 103 .....2, 8, 9, 10

OTHER REFERENCES

Patent Office Manual of Patent Examining Procedure (M.P.E.P.) § 804 (II)(B)(2) (Rev. 5, Aug. 2006) 3

Verma et al., Indian J Pharmacology,
37(5), pp.279-87 (2005) 15

INTEREST OF *AMICUS CURIAE*[1]

The *Patent Docs* weblog is a web-based publication that is operated by its Authors for the purpose of discussing, debating and informing on matters relating to patent law as it is applied to the biotechnology and pharmaceutical industries. The Authors have great personal interest in this area of the law, but the *Patent Docs* weblog is not intended to nor does it dispense legal advice of any kind whatsoever. The Authors have no commercial interest in the parties in this lawsuit (although members of their law firm have represented Eli Lilly and Company in other matters), and are submitting this brief on their own behalf.

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[1] Pursuant to this Court's Rule 37.3(a), counsel for *amicus* secured the consent of all parties ten days prior to the filing of this brief, and letters of consent from all parties to the filing of this brief have been submitted to the Clerk. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* or its counsel made a monetary contribution intended to fund its preparation or submission.

SUMMARY OF ARGUMENT

In *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, the Federal Circuit purported to follow the general guidelines for conducting an obviousness-type double patenting analysis. 611 F.3d 1381 (Fed. Cir. 2010). Instead, however, the Federal Circuit read statements from earlier cases out of context to create an overly broad and rigidly-applied *per se* rule that "obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and that is later claimed as a method of using that compound." *Id.* at 1386.

The Federal Circuit's new *per se* rule changes the law of obviousness-type double patenting in ways that adversely impact the patentability of later-discovered uses for compounds in the chemical, biological, and pharmaceutical arts. Eli Lilly's Petition for Writ of Certiorari presents an opportunity for this Court to correct the Federal Circuit's misstatement of the law in the area of obviousness-type double patenting. Accordingly, this Court should grant Eli Lilly's Petition for Writ of Certiorari and reverse the Federal Circuit's decision because: (i) the Federal Circuit's rigid *per se* rule precludes the courts and the Patent Office from considering the particular facts and circumstances of each case when determining whether obviousness-type double patenting exists; (ii) the Federal Circuit's decision has eviscerated the obviousness-type double patenting doctrine by collapsing it into obviousness under 35 U.S.C. § 103; (iii) the Federal Circuit has misapplied the law by transforming a composition claim into method claims for all uses

disclosed in the prior patent's specification; and (iv) the Federal Circuit's decision creates a bright-line rule that undermines public policy underlying the patent system and curtails innovation.

ARGUMENT

I. The Federal Circuit's Rigid *Per Se* Rule Precludes the Courts and the Patent Office from Considering the Particular Facts and Circumstances of Each Case When Determining Whether Obviousness-Type Double Patenting Exists

Contrary to its own and other established precedent, the Federal Circuit has enunciated a rigidly applied, *per se* rule for applying the judicially created doctrine of obviousness-type double patenting. The Federal Circuit has stated previously that conclusions of obviousness-type double patenting should be based on the facts and circumstances of a given case. *See In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986) ("Each double patenting rejection has to be decided on its own facts."). Likewise, the Patent Office's Manual of Patent Examining Procedure (M.P.E.P.) instructs patent examiners that, during the examination of a patent application, "[e]ach double patenting situation must be decided on its own facts." M.P.E.P. § 804 (II)(B)(2) (Rev. 5, Aug. 2006).

Now, however, the Federal Circuit has reduced the double patenting analysis to a simple if / then test, constituting a *per se* rule that precludes courts and the Patent Office from considering the

specific facts and circumstances of some cases. In particular, for two co-owned patents, if an earlier patent includes claims to a compound and discloses one or more uses for the compound in the specification, under the Federal Circuit's ruling *any* claim(s) in a later patent to *any* method of use disclosed in the specification of the earlier patent (but not claimed) are *per se* invalid based on obviousness-type double patenting. *Sun Pharm. Indus., Ltd.*, 611 F.3d at 1386. According to this rigid rule, there is simply no flexibility for lower courts or the Patent Office to consider any other facts or circumstances that may be relevant to determining whether obviousness-type double patenting should apply to applications claiming methods disclosed (but not claimed) in a related, earlier-filed patent.

The obviousness-type double patenting doctrine is intended, *inter alia*, to prevent the claims of the later patent from improperly extending "protection, beyond the date of expiration of the [earlier] patent, of the very same invention claimed therein . . . or of a mere variation of that invention which would have been obvious to those of ordinary skill in the relevant art." *In re Kaplan*, 789 F.2d at 1579-80. Under the Federal Circuit's rigid rule, however, lower courts and the Patent Office are not free to consider whether a finding of obviousness-type double patenting in some cases would further this policy. Indeed, as the dissent from the Federal Circuit's denial of rehearing *en banc* in this case correctly stated, "[t]he panel failed to explain how Lilly's claims to the use of gemcitabine to treat cancer, discovered after gemcitabine's antiviral use was disclosed in the original application, improperly

extend the patent right to gemcitabine as a compound." *Sun Pharm. Indus., Ltd.*, 625 F.3d 719, 723 (Fed. Cir. 2010) (Newman, J., dissenting).[2] Instead, the panel decision relied merely on a strict application of the rigid rule that "obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound." *Sun Pharm. Indus., Ltd.*, 611 F.3d at 1386. As asserted in the well-reasoned dissent of the Federal Circuit's denial of rehearing *en banc*, "there is no dispute that Lilly would be entitled to a separate patent on the anticancer use if Lilly had not included the disclosure of anticancer use in the specification of the continuation-in-part filed the same day." *Sun Pharm. Indus., Ltd.*, 625 F.3d at 723 (Newman, J., dissenting). However, the strict application of the Federal Circuit's rigid *per se* rule precluded the court from considering the facts and circumstances of this particular case, as the strict application of the Federal Circuit's rigid *per se* rule can be expected to preclude other courts and the Patent Office from considering the facts and circumstances of particular cases in the future.

Similarly, under the Federal Circuit's rigid rule, lower courts and the Patent Office are not free to consider whether a disclosed use in the specification of the earlier patent would actually enable one skilled in the art to practice the method claimed in the later patent. Disclosure relied upon

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[2] Chief Judge Rader, Judge Lourie, and Judge Linn joined Judge Newman's dissent in the 5-4 decision denying Eli Lilly's Petition for Rehearing *en banc*

to support a conclusion of obviousness (or obviousness-type double patenting) must enable one skilled in the art to make and use the claimed invention for its intended purpose. Thus, whether a disclosed use in the earlier patent is enabling might be an important consideration for a lower court or the Patent Office to consider when performing an obviousness-type double patenting analysis *See, e.g., Geo M. Martin Co. v. Alliance Machine Systems, Intern. LLC*, 618 F.3d 1294, 1302-03 (Fed. Cir. 2010); *In re Kumar*, 418 F.3d 1361, 1365 (Fed. Cir. 2005); *Rockwell Intern. Corp. v. U.S.*, 147 F.3d 1358, 1365 (Fed. Cir. 1998); *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). The Federal Circuit's broadly-worded *per se* rule is to the contrary: "obviousness-type double patenting encompasses ***any use*** for a compound that is ***disclosed in the specification*** of an earlier patent claiming the compound and is later claimed as a method of using that compound," *Sun Pharm. Indus., Ltd.*, 611 F.3d at 1381 (emphasis added), regardless of whether the specification constitutes an enabling disclosure on how to make and use a particular compound for the method claimed in the later application.

The Federal Circuit has correctly acknowledged that "double patenting . . . [is] a subject usually fraught with difficulty." *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1281 (Fed. Cir. 1992). The scenarios set forth above illustrate some situations where the Federal Circuit's rigid and broadly-worded *per se* rule is inappropriate and why, instead, "[e]ach

double patenting rejection has to be decided on its own facts." *In re Kaplan*, 789 F.2d at 1580. Indeed, this Court has repeatedly rejected the strict application of rigid rules in the context of other patent-related issues. *See, e.g., Bilski v. Kappos*, 130 S. Ct. 3218, 3326-27 (2010) (rejecting the Federal Circuit's strict application of the machine-or-transformation test as the only standard of assessing patentability under 35 U.S.C. § 101); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (rejecting the Federal Circuit's rigid application of the "teaching, suggestion, or motivation" test for assessing nonobviousness in favor of a more "expansive and flexible approach"); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 122-37 (2007) (rejecting the rigid rule that "a patentee licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of patent" in favor of a more flexible analysis that considers "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment"); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006) (rejecting the Federal Circuit's rigid rule "that a permanent injunction will issue once infringement and validity have been adjudged" in favor of allowing courts to apply traditional principles of equity). The Federal Circuit's use of a rigid rule for assessing double patenting is not substantially different from the rigid rules that this Court has rejected in the past. Accordingly, this Court should similarly reject the Federal Circuit's rigid *per se* rule regarding

obviousness-type double patenting, and instead, allow courts and the Patent Office to consider the facts and circumstances of each particular case when conducting an obviousness-type double patenting analysis.

II. The Federal Circuit Decision Has Eviscerated the Obviousness-Type Double Patenting Doctrine by Collapsing It into Obviousness under 35 U.S.C. § 103

When the Federal Circuit consulted the specification and the claims of the earlier '614 patent against the commonly-owned later '826 patent, it performed a typical obviousness patentability analysis under 35 U.S.C. § 103. This analysis would have been proper if the patent that issued first was held by a separate entity. However, by consulting the specification and conducting a § 103 analysis (while calling it an obviousness-type double patenting analysis), the Federal Circuit rendered irrelevant the fact that the same entity owned both patents. In doing so, the court collapsed obviousness-type double patenting into § 103, effectively eliminating the doctrine. In addition, the Federal Circuit has created a new, non-statutory form of prior art from a patent owner's earlier patents, despite the fact that such art is not made "by another." "By another" has always been an important distinction in U.S. patent law, and for the Federal Circuit to decide now that it is irrelevant is contrary to several provisions of the patent statute. *See, e.g.*, 35 U.S.C. § 102(a) Rather than follow established precedent making it clear that a commonly-owned, prior patent disclosure cited in

support of a double patenting rejection cannot be used as though it were prior art, *see, e.g., General Foods Corp.*, 972 F.2d at 1277, the Federal Circuit instead has spawned a new form of prior art, which changes the inventor's own disclosure into potentially invalidating prior art that operates only against the patentee.

Admittedly, the standard for obviousness-type double patenting is intimately tied to that of obviousness. An obviousness-type double patenting rejection is analogous to (but is not the same as) a failure to meet the non-obviousness requirement of 35 U.S.C. § 103. Thus, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of an obviousness determination, and includes the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The critical difference between an obviousness determination under 35 U.S.C. § 103 and the inquiry used to assess obviousness-type double patenting is that for obviousness, the claims at issue are to be compared to ***prior art taken as a whole***, while for double patenting the comparison is to the claims of the earlier-filed patent. Federal Circuit law makes abundantly clear that the patent underlying the double patenting rejection is not considered prior art. *In re Kaplan*, 789 F.2d at 1579 ("In considering the question [of obviousness-type double patenting], the patent disclosure may not be used as prior art."). Erroneously, the *Sun Pharm.* decision declares that the patentee's disclosure from an earlier patent is now considered prior art. Thus, under this improper precedent there is no distinction between an obviousness-type double patenting analysis and an obviousness inquiry. As such, the

double patenting doctrine has been summarily abandoned.

The Federal Circuit decision in *Sun Pharm.* effectively overturned years of precedent, holding that commonly-owned patents are now to be treated as prior art as if they were owned by separate entities, and has effectively eliminated the doctrine of obviousness-type double patenting, folding the doctrine into an obviousness analysis under 35 U.S.C. § 103. This decision cannot stand.

III. The Federal Circuit Has Misapplied the Law by Transforming A Composition Claim into Method Claims for All Uses Disclosed in the Specification

The Federal Circuit is correct when it states that it followed precedent by first construing the claims, and then comparing the claims of the earlier and later patents to make its obviousness-type double patenting determination. However, the court failed to follow its own precedent by reading limitations from the specification into the claims – there is no other way for the court to conclude that a "method of use" claim is obvious based on a compound claim that recites no specific use. This is the Federal Circuit's self-described "cardinal sin" of patent law. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319-20 (Fed. Cir. 2005) (*en banc*) (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001)). In this case, the limitations read into the gemcitabine compound claim from the specification had a profound effect: the court converted a composition of matter claim into *two* method claims: (1) a method for using

gemcitabine to treat cancer, and (2) a method for using gemcitabine to treat viral infections. The result is a "new" claim construction canon that interprets chemical composition claims to be equivalent to a series of method claims that cover only the uses disclosed in the patent specification. This manner of claim construction cannot stand.

When construing the meaning of a compound claim, only a single utility need be asserted in the specification. Indeed, with respect to utility, that is all the law requires for establishing patentability, occasionally referring to this requirement as "essential utility." *Sun Pharm. Indus., Ltd.*, 611 F.3d at 1386. However, this requirement provides no justification for limiting a claim to a chemical compound to one or more uses disclosed in the specification. To do so would significantly curtail the scope of *all* compound claims by transforming such claims into method of use claims. Such a claim construction would completely reshape the contours of chemical compound claims, rendering them significantly and unnecessarily less robust.

Since the turn of the century, this Court has recognized the importance of preventing limitations in a patent specification from being imported into the patent claims. *McCarty v. Lehigh Val. R. Co.*, 160 U.S. 110 (1895). The Court in *McCarty* explained that if it started to limit claims by including elements not mentioned in the claims, this would create a slippery slope and it would be hard to know where to draw the line. *Id.* at 116; *see also Winans v. Denmead*, 56 U.S. 330, 343 (1853) (discussing how it is unnecessary for patent practitioners to add statements specifying that the claims extend "to the thing patented, however

[varied] its form or proportions" because patent law requires that claims be interpreted as such even without these words). Furthermore, the Court has discussed how importing limitations from the specification might legally permit the public to replicate mass quantities of the invention simply by altering "its form or proportions." *See Winans*, 56 U.S. at 343.

In *Sun Pharm.*, the Federal Circuit violated these well-accepted doctrines of patent law in finding a method of using gemcitabine for anticancer use to be invalid for obviousness-type double patenting based on a claim to the gemcitabine compound and disclosure of additional uses in the prior patent's specification. By treating the '614 patent in its entirety as prior art and consulting the specification rather than just the claims for assessing invalidity due to obviousness-type double patenting, the Federal Circuit overturned years of obviousness-type double patenting law and effectively eliminated the doctrine. The Federal Circuit cannot escape this conclusion by arguing that it merely "construed" the claims of the earlier patent prior to performing a comparison with the claims of the later application. In performing its claim construction, the court improperly read into the claims limitations that transformed the scope and meaning of the claim, from a claim to a compound *per se* to a claim to a compound limited by all of the uses disclosed in the specification. A compound claim, with no limitation on use described in the claim, simply cannot render obvious any and all disclosed methods of using that compound to treat any and all diseases. Because the Federal Circuit committed legal error in so construing these claims, its decision cannot stand.

IV. The Decision below Creates A Bright-Line Rule That Undermines Public Policy Underlying the Patent System and Curtails Innovation

The decision below warrants review, because it undermines the important and well-settled public policy of encouraging patent applicants to disclose new and useful advances in technology. This Court on several occasions has stated that public disclosure is the cornerstone of the implicit bargain on which the patent system is based. *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 626 (2008) ("[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is 'to promote the progress of science and useful arts.'") (*quoting Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917)); *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology.").

In preventing Eli Lilly and Company and similarly situated applicants from claiming a method that consists of a new way of using a previously known product in order to achieve a new result, the decision below creates an improper and damaging bright-line rule. First, the Federal Circuit's bright-line rule is blatantly inconsistent with the patent statute that identifies as patentable "any new and useful improvements" of a process, machine, manufacture, or composition of matter. 35 U.S.C. § 101 (2000). Second, the Federal Circuit's bright-

line rule goes against this Court's and the Federal Circuit's line of cases holding that new uses of old products or processes are indeed patentable subject matter. *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 18 (1892) ("If an old device or process be put to a new use which is not analogous to the old one, and the adaptation of such process to the new use is of such a character as to require the exercise of inventive skill to produce it, such new use will not be denied the merit of patentability."); *Catalina Marketing International, Inc. v. Cool Savings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) (explaining that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus). Finally, the Federal Circuit's bright-line rule provides no public policy rationale for its unwarranted expansion of the doctrine of obviousness-type double patenting. This judicial doctrine was created to "prevent a patentee from obtaining a timewise extension of [a] patent for the same invention or an obvious modification thereof" by prohibiting "claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1375 (Fed. Cir. 2008). The obviousness-type double patenting doctrine was not intended as a mechanism for the courts to penalize applicants for publicly disclosing their follow-on research, which is particularly important in the field of biotechnology where applicants routinely carry out

investigations of new properties and new uses for their inventions during clinical use.[3]

The decision below undermines public policy underlying the patent system and would curtail innovation. In fact, the position taken by the Federal Circuit is also inconsistent with the sound policy of encouraging follow-on investigations by allowing patentees to introduce into evidence the results of experiments carried out after the patent grant in response to litigation attacks on validity. *Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) ("There is no requirement that an invention's properties and advantages were fully known before the patent application was filed, or that the patent application contains all of the work done in studying the invention, in order for that work to be introduced into evidence in response to litigation attack.").

Finally, the decision below undercuts the incentive for applicants, particularly applicants in the chemical, pharmaceutical, and biotechnological arts, to not only disclose the results of their follow-on

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[3] For example, pharmaceutical drugs that were developed for later-discovered uses include allopurinol (initial use: antineoplastic, additional or new primary use: treatment of gout); amantadine (initial use: antiviral; additional or new primary use antiparkinsonism), atomoxetine (initial use. antidepressant, additional or new primary use: attention deficit hyperactivity disorder); estrogens (initial use replacement therapy; additional or new primary use contraception), pemetrexed (initial use mesothelioma, additional or new primary use: lung cancer); raloxifene (initial use. contraceptive; additional or new primary use: osteoporosis); sildenafil (initial use angina, additional or new primary use: male erectile dysfunction). Verma *et al* , *Indian J Pharmacology*, 37(5) 279-87 (2005)

research, but to engage in the follow-up research into new uses for old drugs. Drug development is a capital-intensive and a time-consuming process. Introducing a successful new drug to market may take more than a decade and cost upwards of one billion dollars. Discovering new uses for old drugs may significantly reduce the required resources to bring new drugs to market and increase the drugs' safety and efficacy. The decision below, however, will have a chilling effect on these pharmaceutical research efforts, because without the opportunity to obtain meaningful patent protection, pharmaceutical companies are unlikely to engage in the development of cost-effective treatments that are beneficial to patients.

CONCLUSION

The Federal Circuit's new *per se* rule changes the law of obviousness-type double patenting in ways that adversely impact the patentability of later-discovered uses for compounds in the chemical, biological, and pharmaceutical arts. Eli Lilly's Petition for Writ of Certiorari presents an opportunity for this Court to correct the Federal Circuit by striking down the rigid rule that "obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound," *Sun Pharm. Indus., Ltd.*, 611 F.3d at 1381. Accordingly, this Court should grant Eli Lilly and Company's Petition for Writ of Certiorari and reverse the Federal Circuit's decision below.

Respectfully Submitted,

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